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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------------|--------------------------------|------------------|
| 10/511,794 | 03/17/2005 | Jorge Victor Gailondo Cowley | 976-20PCT/US | 6673 |
| 23869 | 7590 | 03/06/2007 | | |
| HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791 | | | EXAMINER BRISTOL, LYNN ANNE | |
| | | | ART UNIT 1643 | PAPER NUMBER |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 31 DAYS | 03/06/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

14

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|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/511,794 | Applicant(s) GAILONDO COWLEY ET AL. | |
| | Examiner Lynn Bristol | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Lack of Unity Restriction

1. Claims 1-31 are all the pending claims for this application and subject to lack of unity restriction.
2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is an antibody fragment for a scFv obtained from the CB-CEA.1 Mab (anti-CEA) and specific for CEA. In view of this, Tormo et al. (APMIS 97(12):1073-80 (1989)) in view of Hollinger et al. (PNAS 90:6444-6448 (1993); cited in the IDS of 1/24/05) disclose the technical feature, and therefore, the claims are not linked to form a single inventive concept. Tomoro discloses an anti-CEA (CB-CEA-1) murine monoclonal antibody useful for diagnosing and treating tumors expressing CEA. Hollinger discloses recombinant antibody fragments using variable domains encoded by genes from mouse hybridomas to make constructs for expressing scFv, bivalent and bispecific antibody fragments that have the advantages of retaining the antigen recognition of the parent antibody, being small in size, assemble in vivo and harvested directly from culture supernatant. One skilled in the art would consider combining the techniques of Tomoro and Hollinger to obtain an improved antibody fragment having at least the binding properties of the parent antibody and the advantages of being readily producible as a properly

assembled and secreted antibody fragment by transfected cells in vitro or in vivo.

Therefore the technical feature recited in claims 1-31 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

3. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11 and 15-25, drawn to a monomeric scFV antibody fragment recognizing human CEA and obtained from the hybridoma producing the CB-CEA-1 Mab, fragments comprising the amino acid sequence of SEQ ID NOS: 16 and 17, scFv produced by recombinant cells or organisms, scFv antibodies used for identifying or treating or radiolocalizing human CEA-expressing tumors, and pharmaceutical compositions for treatment or radiolocalization of tumors expressing CEA.

Group II, claim(s) 12-14 and 26-31, drawn to recombinant cells expressing monomeric scFV antibody fragment recognizing human CEA and obtained from the hybridoma producing the CB-CEA-1 Mab, recombinant multicellular organisms expressing the the scFV antibody fragments, and vectors encoding the scFv antibody fragments.

4. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Tomoro in combination with Hollinger the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claims 1-31 is not special.

Art Unit: 1643

5. Inventions of Groups I and II represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Group I is a protein for a scFv antibody fragment and Group II is a recombinant living cell or multicellular organism comprising a vector encoding the scFv antibody fragment, or a vector encoding the scFv antibody fragment. The inventive products are different in structure, are made by different processes, and one of skill in the art would not expect the inventive products to function in the same capacity. The examination of all groups would require different searches in the U.S., international and foreign patent literature and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I and II are patentably distinct.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion


Art Unit: 1643

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SENIOR PATENT EXAMINER